K003856

BIOMERICA

FEB 21 2001

510-K

Summary Statement

Biomerica Inc., *EZ-HCG™* urine test device is a one step immuno-assay for a rapid, qualitative determination of human Chorionic Gonadotropin (hCG) in urine for early detection of pregnancy.

The device is an *in vitro diagnostic* test kit.

The *EZ-HCG™* test device consists of a chromatographic absorbent membrane strip and a combination of monoclonal and polyclonal antibodies that selectively identify hCG in test samples with a high degree of sensitivity. Within five minutes, levels of hCG as low as 10 mIU/ml can be detected.

Biomerica's *EZ-HCG™* is a generic type device using a plastic strip affixed with a porous membrane with two antibodies immobilized on it; a fiber glass pad soaked and dried with an antibody coupled with gold particles and a filter strip. The plastic strip is encased inside a plastic cassette with two windows – one for sample addition and the other for viewing the results.

Data submitted in this 510-K Premarket notification is correct and has been compared to be substantially equivalent to a 510(k) cleared commercially available predicate devices in the market, manufactured by Biomerica Inc., and Quidel Corporation, San Diego. California.

This device has no environmental impact.

The performance data and clinical data is on file and is available to any qualified individual upon request. Biomerica is responsible and attests that all information submitted is true and authentic to the best of our knowledge.

Sincerely,

Jay Singh
Chief Operating Officer.

Francis Capitanio
President.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 21 2001

Mr. Jay Singh
Chief Operating Officer
Biomerica, Inc.
1533 Monrovia Avenue
Newport Beach, California 92663

Re: K003856
Trade Name: EZ-HCG™ Urine (Pregnancy Test)
Regulatory Class: II
Product Code: JHI
Dated: January 16, 2001
Received: January 23, 2001

Dear Mr. Singh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003856

Device Name: ***EZ-HCG™ Urine* (Pregnancy Test)**

Indications for use:

Biomerica's *EZ-HCG™* is an in vitro Diagnostic test system for the rapid, qualitative determination of total Human Chorionic Gonadotropin (HCG) in human urine. It is intended to be used for the early detection of pregnancy

EZ-HCG™ test device will be used by qualified medical technicians in clinical laboratories (Labs) and physicians office laboratories (POL's). It is not an invasive or life threatening device and the results thereof must be used with other relevant clinical data to affect true diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the counter use____
(Per 21 CFR 801,109)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003856

(Optional Format 1-2-96)